

REMARKS

Claims 1-15 and 17-19 are pending and stand rejected. At the outset, Applicants note that claims 1-19 are incorrectly listed as pending in the present Office Action. Claim 16, however, was cancelled in the Amendment and Response filed on July 21, 2003. Correction is respectfully requested.

Applicants amend independent claim 1 to clarify the claimed invention, and in particular to clarify that the control unit is effective to receive and compile a database of the sensor output signals, and to communicate a delivery signal that is continuously adjusted based on the database of sensor output signals to the pump to deliver the drug at a rate and for a duration effective to achieve a desired biochemical parameter within a predetermined range. Support for this amendment can be found throughout the specification, for example, at page 10, lines 5-22, and in originally-filed claim 16. Claims 7 and 14 are amended to correct punctuation and/or typographical errors. No new matter is added.

Applicants also add new claim 20, which recites a method for delivering an effective amount of a drug to a subject. The method includes the steps of sensing one or more biochemical parameters in a subject in response to the delivery of a drug to produce sensed signals, creating a dose-response database from the sensed signals, modeling appropriate pump control parameters for maintaining desired conditions based on the dose-response database, delivering a drug to a subject from a drug delivering pump operated under the appropriate pump control parameters, and repeating the step of sensing one or more biochemical parameters to modify the dose-response database and to model appropriate pump control parameters. Support for new claim 20 can be found throughout the specification, for example, at page 10, lines 16-22. No new matter is added.

Applicants respectfully request reconsideration of the present application in view of the amendments set forth above and the remarks below.

Rejection Pursuant to 35 U.S.C. §102

Claims 1-19 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,730,125 of Prutchi et al. (Prutchi). The Examiner argues that, at Col. 13, line 45 to Col. 14, line 5, Prutchi discloses a drug delivery system and method that stores dose response information and that adjusts the desired biochemical parameters in response to the monitored and stored information. The Examiner further states that “features upon which applicant relies (i.e., storing sensed data) are not recited in the rejected claim(s).” Applicants respectfully disagree.

Regarding the latter assertion by the Examiner, Applicants have amended independent claim 1 to clarify that the control unit is effective to receive and compile a database of the sensor output signals, and that it is effective to communicate a delivery signal adjusted based on the database of sensor output signals to the pump to deliver a drug at a rate and for a duration effective to achieve a desired biochemical parameter within a predetermined range. Independent claim 14 similarly recites a method of drug treatment using a drug delivery system having a control unit with a processor that “compiles a database of sensed data and response data, and [that] responds to the compiled data to create and adjust a treatment model.” Accordingly, the features upon which applicant relies are specifically recited in the rejected claims. These features are also recited in new claim 20.

With regard to the Prutchi reference, the features recited in independent claims 1 and 14, as well as new claim 20, are not taught or even suggested by Prutchi. The Examiner refers to Col. 13, line 45 to Col. 14, line 5, arguing that these passages disclose a drug delivering system that can store dose response information and that adjusts the desired biochemical parameters in response to such stored information. This is incorrect. The cited passages in Prutchi disclose an implantable medical device that utilizes telemetry to transmit data and instructions. In particular, Prutchi discloses an external probe that transmits instructions which can be used to reprogram the microprocessor or which can be stored in a memory package. Prutchi also states that data gathered by the implanted device can be transmitted to the external probe. Accordingly, Prutchi is strictly limited to a conventional drug delivery pump that can

send and receive data - - the data is not internally processed to automatically adjust the operating parameters of the pump. Prutchi therefore does not teach or even suggest the drug delivery pump and methods recited in claims 1, 14, and 20 of the present invention.

Prutchi also fails to teach or even suggest a drug delivery pump that is capable of *continuously adjusting* the delivery instructions based on a database of sensor output signals, as is also required by claim 1 of the present invention. As previously stated, the Prutchi system utilizes a probe that is placed externally, and in proximity to the pump to transmit data to a from the pump. Since the probe is external, and thus it is not always in communication with the control unit in the pump, the delivery instructions can not be continuously adjusted. Claim 1 therefore further distinguishes over Prutchi.

For the same reasons, claim 14 also further distinguishes over Prutchi since claim 14 requires a *closed loop* feedback cycle to regulate delivery of the drug from the infusion pump so as to maintain the sensed biochemical parameter or event within a predetermined range. A pump requiring an external probe to control drug delivery, as disclosed by Prutchi, is not a *closed loop* system.

In sum, independent claims 1, 14, and 20 distinguish over Prutchi and therefore represent allowable subject matter.

Dependent claims 2-13, 15, and 17-19 are allowable at least because they depend from an allowable base claim. Applicants also note that several of the dependent claims further distinguish over Prutchi, and it appears that the Examiner has failed to consider these claims and to indicate that these claims represent allowable subject. Claim 7, for example, requires that the sensor be implanted at a location that is remote from the location of the distal end of the delivery conduit. Prutchi specifically requires a system in which the sensors are disposed and sealed within the housing containing the pump. Claim 11 also distinguishes over Prutchi since claim 11 recites a sensor having an array of optical fibers, and Prutchi does not teach or even suggest any type of array of optical fibers. Accordingly, in the event that the Examiner

continues to reject the pending claims, consideration of each dependent claim is respectfully requested.

Conclusion

In view of the amendments and remarks above, Applicants submit that claims 1-15 and 17-20 are in condition for allowance. In the event that the above amendments and remarks are not deemed to place this case in condition for allowance, an opportunity to interview with the Examiner is requested. Applicants encourage the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

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Respectfully submitted,



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